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**SOLICITATION FOR APPLICATIONS TO ESTABLISH CENTERS OF EXCELLENCE
IN TOBACCO USE TREATMENT OUTCOMES RESEARCH (TUTOR)**

1. This Notice announces the opportunity for Department of Veterans Affairs (VA) medical facilities to compete for funding to establish one or more peer-reviewed Office of Research and Development Centers of Excellence in Tobacco Use Treatment Outcomes Research (TUTOR).

2. Purpose, Background, and Rationale

a. **Purpose.** The purpose of TUTOR is to enhance VA's capacity to conduct a broad spectrum of interdisciplinary research on healthcare problems pertaining to tobacco use (and related disorders) within Veterans Health Administration (VHA). Across the span of its 5-year funding award, TUTOR is expected to develop (or to nurture) interdisciplinary research expertise that encompasses most, if not all, of basic biomedical science, applied clinical research, applied health systems research, and rehabilitation outcomes research. Accordingly, TUTOR's 5-year strategic and operational plans for accomplishing its research mission are expected to be guided by a comprehensive framework (e.g., a bio-behavioral theory of addiction) regarding the etiology, diagnosis, treatment, and rehabilitation of tobacco use and related disorders (e.g., chronic obstructive pulmonary disease (COPD), ischemic heart disease (IHD), hypertension, or cancer) at the healthcare provider level.

b. **Background.** Tobacco use is a potent cause of potentially preventable morbidity and mortality for the nation's veterans, and it accounts for a substantial portion of the nation's overall healthcare costs. Recognition is growing, however, that more favorable outcomes may be achievable for the treatment of tobacco use (including the prevention of remission) at the primary care provider level.

c. **Rationale.** With its extensive experience in medical education and research, its national healthcare delivery system (with approximately 1,100 sites of care delivery organized into 22 Veterans Integrated Service Networks (VISNs)), and its focus on the provision of high quality care for a defined population of patients, VHA provides researchers with an opportunity for the comprehensive study of the etiology, diagnosis, treatment, and rehabilitation of tobacco use among the nation's veterans. Accordingly, TUTOR will be expected to:

(1) Provide academic leadership for VA providers who seek continual, ongoing improvements in tobacco use treatment outcomes for the nation's veterans, and

(2) Help educate VA providers in the innovative transport of effective treatments to other healthcare delivery settings.

3. Program Policies

a. This solicitation provides VA medical facilities with the opportunity to apply for 5 years of core support funding to establish a research center for the timely and effective accomplishment of a series of well-delineated programmatic goals and objectives. Core support funding is expected to facilitate the recruitment and development of a stable "critical mass" of administrative, professional, and technical staff skills, knowledge, and experience, sufficient to

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help extend the benefits of tobacco use treatment outcomes research throughout VHA's healthcare delivery system.

b. TUTOR's leadership is expected to develop strategic and operational plans regarding the use of its technical expertise and other developed resources, for the purpose of becoming significantly leveraged by the completion of its 5-year funding award. TUTOR's staff is expected to facilitate the development of future VA knowledge and practice in systems thinking and redesign, for the purpose of generating continuous quality improvements for tobacco use interventions.

c. Proponents are expected to present the four basic, interlocking components of TUTOR's (preliminary) strategic and operational plans in their Center proposal (see subpar. 7a).

d. TUTOR's leadership is expected to "add value" for VA's tobacco use treatment outcomes research agenda, by:

(1) Leveraging the Center's limited core support funds at the local, VISN, or national level(s) to achieve maximum research potential.

(2) Identifying high priority areas for future research initiatives by VA's Office of Research and Development, regarding the treatment of veterans' tobacco use and related disorders.

(3) Designing collaborative research or demonstration projects of sufficient scope and duration to achieve definitive findings in support of VA policy decisions at the national level.

(4) Facilitating the training of new VA investigators in outcomes research methodologies, with a specific generic focus on the treatment of addictions.

(5) Developing innovative strategies to broadly, effectively, and efficiently disseminate pertinent, evidence-based knowledge regarding targeted tobacco use interventions.

(6) Providing technical support or assistance, on behalf of the Chief Research and Development Officer, to help sustain VHA's overall quality enhancement research agenda.

e. One or more Centers may be funded for up to 5 years, beginning approximately April 1, 1999. Each TUTOR can expect to receive up to \$500,000 annually for recurring core support costs. Competitive renewal (after 5 years) is possible, based on the satisfactory review of a scientifically meritorious Center continuation application and the availability of funds.

f. In addition to recurring core support funds, each TUTOR application may include a request for up to \$100,000 (non-recurring) for specialized shared equipment. Well-justified requests for major equipment items in excess of \$100,000 will be considered administratively, if the request also includes documentation of anticipated shared support by the applicable VA medical facility, VISN, or affiliated institution. Shared support may include, for example, cost sharing, facility renovation or equipment housing costs, service contracts on equipment, or costs for personnel to oversee use of the equipment or facility.

g. Each TUTOR is expected to submit an annual report for administrative review. Continuation of core support funding is based on the satisfactory accomplishment of selected performance-based measures, that will be included in each TUTOR's formal (approved) 5-year strategic and operational plans. TUTOR's annual report may be accompanied by necessary changes in its strategic and operational plans, especially to correct any performance deficits.

4. **Program Requirements**

a. All TUTOR applications will be peer-reviewed, with centralized funding awards contingent on availability of funds and receipt of a sufficient number of applications with high scientific merit.

b. No preliminary TUTOR Letter of Intent (LOI) is required.

c. Applicant sites may be a single VA medical facility or a consortium of collaborating VA medical facilities. All applicant sites, including at least the lead site for a consortium proposal, should have a formal academic affiliation with a School of Medicine or a School of Public Health that has well-established resident expertise in the:

(1) Treatment (e.g., bio-behavioral, clinical, or pharmacological) of addictions, and

(2) Applicable use and appropriate interpretation of outcomes research methodologies.

d. Initial TUTOR core support funding awards are expected not to exceed (NTE) \$500,000 annually, for a maximum duration of 5 years. (Full-time Employee Equivalent (FTEE) requests are typically expected NTE 5.5 for a single-site TUTOR application, and 7.0 for a multi-site TUTOR application.)

e. Subsequent to the scientific review process, VA's Office of Research and Development may conduct formal administrative site visit reviews.

f. TUTOR's Director (Principal Investigator) must be eligible to receive VA research support. New non-clinician scientists must have established eligibility prior to submission of the proposal. Clinician-investigators who have less than a 5/8th's salaried position with a VA medical facility must have been deemed eligible within the previous 12 months (i.e., preceding the TUTOR application deadline). Non-VA Co-Investigators, consultants, and support staff may be reimbursed through diverse administrative mechanisms, such as contracts or Intergovernmental Personnel Act (IPA) agreements.

g. Either TUTOR's Director, or its Associate Director, is expected to be an eligible VA clinician-investigator, for whom the local VA medical facility contributes release time. In turn, VA's Office of Research and Development will provide salary and Full-time Equivalent (FTE) support for an eligible VA non-clinician scientist, who will serve conversely as TUTOR's Director or Associate Director.

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h. The following award schedule is projected:

(1) Request for TUTOR applications issued by VHA Headquarters (12): August 31, 1998.

(2) An unbound original and twelve copies of each TUTOR proposal are due in Health Services Research and Development (HSR&D) Service (124C), VHA Headquarters, 810 Vermont Avenue, NW, Washington, DC 20420: December 2, 1998.

(3) Reviews completed and notifications provided (for all TUTOR applicants): March 1, 1999.

(4) Administrative site visits (in VHA Headquarters) completed (for TUTOR semi-finalists only): March 12, 1999.

(5) Administrative site visits (at local facility) completed (for TUTOR finalists only): March 26, 1999.

(6) TUTOR start-up: April 1, 1999 (assuming completion of satisfactory site visit reviews).

i. Within 6 months of receipt of (first-year) core support funding, TUTOR's leadership will be expected to provide VA's Chief Research and Development Officer with the 5-year strategic and operational plans (with appropriate budget adjustments) for the Center, for final approval. These plans will be used, in part, to measure TUTOR's performance over the remainder of its 5-year funding award.

5. Directions and Format

a. The application consists of six parts:

(1) Letters of Transmission (no page limits). Signed and dated letters of transmission should discuss any VA medical facility or VISN commitments to:

(a) Support a nationally networked TUTOR;

(b) Provide up to 50 percent release time for TUTOR's clinician Director or its clinician Associate Director;

(c) Provide administrative infrastructure support for TUTOR; and

(d) Support TUTOR's academic mission, especially the integration of future VA knowledge and practice regarding tobacco use interventions.

(2) Abstract (one-page maximum). The abstract should be suitable in content for announcements of a "public relations" variety. A structured abstract format, similar to that used for all VA Office of Research and Development annual reports, is preferred.

(3) Executive Summary (three pages maximum; “stand-alone” document). **NOTE:** *Exclusive of the assigned reviewers for the main proposal, the Executive Summary is the only document that ALL members of the Review Committee will be expected to review (i.e., for comparative purposes).*

(4) Center Proposal (twenty pages maximum; “stand-alone” document) To be single-sided copies only, on standard-sized white paper; typed single-spaced, with a font size no smaller than twelve characters per inch). **NOTE:** *The Center Proposal is the only document that assigned reviewers for the TUTOR application will be expected to review. The proposal is expected to provide the conceptual underpinning for TUTOR’s subsequent development (i.e., if the proposal is approved and funded) of formal 5-year strategic and operational plans to accomplish its research mission.*

(5) Program 824 Budget Request(s) (no page limits; see Att. A, i.e., budget format, HSR&D Document #RES-22-351).

(a) Office of Research and Development funding cannot be provided for physician salary support. Instead, VA medical facilities or their respective VISNs are expected to support individual TUTOR applications, and to provide up to 50 percent time and salary support for TUTOR’s clinical leadership (i.e., as its Director or as its Associate Director).

(b) Applicants are encouraged to allocate approximately 10 percent of their annual core support funds for enhancements to TUTOR’s system-wide information dissemination capabilities (e.g., for the development of Web pages) and the ongoing training needs of TUTOR’s internal (core) staff.

(c) Recurring and non-recurring annual budget requests are to be submitted in standard HSR&D Service budget formats (for receipt of Program 824 funds). Distributed on a quarterly basis, HSR&D budgets typically include:

1. Salary and FTE support for VA employees only;
2. Travel for VA employees only, and
3. “All Other” funds (see Att. A, HSR&D Document #RES-22-351).

(d) Complete an annual TUTOR Program 824 budget format (to be disbursed on a quarterly basis) for each of the 5 years for which direct core support funding is being requested from VA’s Office of Research and Development.

(e) Equipment requests (non-recurring) are to be appended (to the appropriate annual budget request), as a supplemental (non-core support) budget request.

(f) For a consortium TUTOR application, complete separate annual budget formats for each participating VA medical facility.

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(g) On an annualized basis only, identify all non-HSR&D Service contributed dollars (e.g., Medical Research Service, Program 821 funds; Patient Care Services, Program 870 funds) from all sources (e.g., participating VA facilities, other offices in VHA Headquarters, and non-VA public or private sources). Include both monetary and in-kind contributions (e.g., equipment, maintenance contracts, or supplies).

(h) Justify all budget requests, with explicit reference(s) to TUTOR's main proposal, that is, as the conceptual underpinning for TUTOR's subsequent development of its formal 5-year strategic and operational plans.

(i) All proposed personnel and budgetary practices for TUTOR must be consistent with existing Federal rules and regulations.

NOTE: *These Program 824 budget requests are the only documents administrative site visit reviewers of scientifically meritorious TUTOR applications will be expected to review.*

NOTE: *For an operational TUTOR, approval of its annual budget request will be subject only to the availability of funds, a satisfactory administrative review of TUTOR's annual report, and TUTOR staff's compliance with all existing federal rules and regulations, that is, assuming that TUTOR's annual budget request does not exceed its initial target allowance (i.e., expected to be \$500,000 or less in direct core support costs) for the upcoming fiscal year.*

(6) Appendices (cannot exceed 100 pages total).

(a) Supplemental materials must be limited to 100 pages. All letters of support, biographical materials (including a curriculum vita for TUTOR's Director), publication reprints, and human, animal, or biosafety approvals (if applicable) are included in this total page limitation.

(b) Exclusive of this total page limitation, provide a listing of appendices that includes appropriate numbers and titles. The label for each appendix should reference clearly its relationship to the applicable portion of the main proposal.

b. Except for required letters of transmittal and TUTOR annual budget requests, reviewers will receive ONLY the maximum number of pages specified for any particular part of the TUTOR application. All excess pages will be removed administratively, without exception.

c. Append the following statement, signed by the applicant: "VA is authorized to share copies of all materials included in this TUTOR application, for the purpose of review."

d. Applications must include the required information in the order shown in subparagraph 7a.

7. Required Information

a. Within the overall 20-page limit, TUTOR's Center Proposal should address four key (equally-weighted) themes that are expected to have relevance for completion of TUTOR's formal 5-year strategic and operational plans. These themes are:

- (1) Interdisciplinary, scientific research focus;
- (2) Outcomes research methodological expertise;
- (3) Administrative infrastructure; and
- (4) “Added value” (relevance) for VHA.

b. For the reader’s convenience, the selective comments follow, for each of TUTOR’s four key themes:

(1) Interdisciplinary, Scientific Research Focus

(a) TUTOR should organize the diverse array of information on tobacco use treatment outcomes research, for the ultimate benefit of potential consumers. Ranging across the full spectrum of scientific research disciplines, this may encompass such research topics as:

1. The etiology of “tobacco use disorder” among the nation’s former combat veterans;
2. Reversal of smoking rates by dopamine agonism and antagonism;
3. The role of serotonin in cigarette smoking, “cravings,” and psychiatric symptoms;
4. Oral sensory replacement(s) for smoking cessation;
5. Efficacy (or cost-effectiveness) of tobacco use interventions, including the management of unintended weight gain, excessive VA pharmacy costs for pharmaceuticals, or the feasibility of successfully implementing AHCPR’s smoking cessation practice guidelines; and
6. Longer-term “quality-of-life” implications for treatment failures.

(b) Applicants are encouraged to explain precisely how TUTOR’s long-term (5-year), interdisciplinary research goals and objectives will have direct, measurable, and sustainable impacts on tobacco use by veterans and on related provider practices within VHA.

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(2) Outcomes Research Methodological Expertise_

(a) TUTOR will assemble a core staff with appropriate expertise and experience to implement the goals and objectives of its 5-year strategic plan. Whether its long-term research plans are based primarily on a public health perspective; derived from a theory regarding the treatment of other addictions; or focused pragmatically at the primary care provider level, TUTOR should be able to provide potential consumers with a conceptual underpinning as to whether a particular intervention is effective for particular populations of veterans at specified risks for certain healthcare outcomes.

(b) Applicants should explain precisely how the Center will assemble sufficient core and affiliated staff experience and expertise to effectively accomplish TUTOR's stated long-term research goals and objectives, with a special emphasis on TUTOR's plans to integrate basic research and clinical applications.

(c) Ideally, TUTOR's capacity to conduct outcomes research will be linked conceptually with a discussion of interdisciplinary research projects on tobacco use and related disorders among the nation's veterans.

(3) Administrative Infrastructure

(a) TUTOR should achieve its stated long-term research goals and objectives in a timely fashion. For example, individual investigators will continue to receive peer-reviewed funding awards for the initiation of large-scale smoking cessation research projects within VHA. Accordingly, TUTOR applicants are invited to review their:

1. Current (or expected) research, educational, clinical, and administrative resources and their expected availability to implement the TUTOR program at the local VA medical facility or VISN level;
2. Governance mechanisms (e.g., composition and functions of the TUTOR's Steering Committee);
3. Scientific qualifications and other leadership qualities of TUTOR's Director and other key investigators;
4. Staff development plans (e.g., mentoring capabilities, capacity for joint academic appointments, and current or potential pre- or post-doctoral training opportunities); and
5. Program evaluation plans for documenting achievement of TUTOR's goals and objectives.

(b) With due regard for the 20-page limitation for the Center proposal, TUTOR applicants may wish to provide details as to how their administrative infrastructure is expected to be proactively involved in the accomplishment of TUTOR's goals and objectives. This may include, for example, careful attention to the local, regional, or national composition of the Steering (Advisory) Committee; judicious consideration of diverse ways in which individual Committee members may be able to help TUTOR (e.g., access to unique or scarce resources, "public relations" capabilities, or assistance with recruitment plans); and references to the appendices that may include written Steering Committee minutes, letters of support with explicitly stated resource commitments from the partners involved, or significant memoranda of understanding with collaborating institutions.

(4) "Added Value" (Relevance) for VHA

(a) Beyond the mere extension of existing research agendas, TUTOR applicants are invited to review their plans for enhancing the relevance of interdisciplinary research for VHA's clinical practices. This may include, for example, the implementation of automated tobacco user identification systems or computer-generated reminder systems for provider-initiated tobacco interventions.

(b) With due regard for the 20-page limitation, TUTOR applicants are reminded that many VA researchers in smoking cessation also have demonstrated corollary clinical, educational, or research interests that may have direct or indirect relevance for the leveraging of the Center's limited core support assets. In addition, TUTOR applicants are reminded of service obligations, on behalf of VA's Chief Research and Development Officer.

8. Review Guidelines

a. TUTOR applications will be reviewed and rated by a panel consisting of VA and non-VA administrators, clinicians, educators, and researchers. Proposal ratings will be based on scientific and technical merit, adherence to the overall goals of VA's Office of Research and Development, and responsiveness to the solicitation.

b. The review panel will make its recommendations to VA's Chief Research and Development Officer. Based on these recommendations, the Chief Research and Development Officer may elect to use administrative site visit reviews as part of the final funding determination process. They may be used to gather information on any aspect of the proposed TUTOR, including its facilities and staff, the scope and duration of various institutional commitments, and planned approaches by its leadership for the ongoing management and periodic evaluation of its research program(s).

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9. **Inquiries.** Direct any questions regarding the TUTOR application process to: Charles E. Welch, III, Ph.D., Assistant Director, Health Services Research and Development Field and Core Support Programs (124C), at (202) 273-8253 [e-mail: charles.welch@mail.va.gov].

10. **Responsible Office.** The Office of Research and Development (12) is responsible for the contents of this Notice.

11. **Recertification.** This VHA Notice will be recertified on or before the last working day of August 2003.

S/ by Thomas Garthwaite, M.D. for
Kenneth W. Kizer, M.D, M.P.H.
Under Secretary for Health

Attachment

DISTRIBUTION: CO: E-mailed 9/1/98
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ATTACHMENT A

BUDGET FORMAT
(PROGRAM 824) FY 1999

Health Services Research and Development (HSR&D)
DOCUMENT RES 22-351

<u>Expense Description</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>Sub-Total</u>	<u>Contributed Total (1)</u>	<u>Total Direct Cost</u>
<u>Personnel (824.001) (2)</u>							
Principal Investigator Harry Brown (GS 12/1) (%)						7,938	7,938
Project Director Peter Gray (GS 11/2) (%)	11,083				11,083		11,083
Research Assistants Joyce Jones (GS 7/1) (%)		1,948			1,948		1,948
Carol Snead (GS 7/1) (%)		1,948			1,948		1,948
Data Analyst Edward Kane (GS 7/1) (%)		2,825	5,659	8,474	16,958		16,958
Sub-Total (salaries)	11,083	6,721	5,659	8,474	31,937	7,938	39,875
Fringes (NTE 26%)	2,882	1,747	1,471	2,203	8,303	2,064	10,367
Sub-Total (Personnel)	13,965	8,468	7,130	10,677	40,240	10,002	50,242
<u>Other: (824.001)</u>							
Consultant Services	200			200	400	300	700
Equipment	75	75	75	75	300		300
Supplies	90	90	90	90	360		360
Miscellaneous (3)					0		0
Computer Services			250	250	500		500
Sub-Total (Other)	365	165	415	615	1,560	300	1,860
<u>Travel: (824.007)</u>				500	500		500
GRAND TOTAL	14,330	8,633	7,545	11,792	42,300	10,302	52,602
<u>TOTAL FTEE</u>	.3	.3	.2	.3	1.1	.2	1.3

(1) Contributed services refer to personnel or other resources needed to conduct a project and for which no Program 824 funds or personnel ceiling are requested from the HSR&D Service.

(2) List personnel individually: title and name (grade and step), (percent effort).

(3) List by individual components and justify within accompanying text.

Signatures required: Program Director (or appropriate Principal Investigator);
(budget requests) Associate Chief of Staff for Research and Development (or ERDO/WRDO); and VA
medical facility Director